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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/473,904	12/28/99	CHEE	M A-67493-2RFT

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EXAMINER

PRASTHOFER, T

ART UNIT	PAPER NUMBER
1627	11

DATE MAILED: 05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/473,904

Applicant(s)

CHEE ET AL.

Examiner

Thomas W Prasthofer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Detailed Action

Status of the Application

Receipt is acknowledged of a Petition for Extension of time and a Response to Restriction Requirement with Amendment on April 18, 2001 (Paper Nos. 9 and 10).

Status of the Claims

Claims 1-19 were pending in the application. Claims 1-17 were canceled by Applicant in Paper No. 10. Applicant elected Invention II (claims 18 and 19) in response to the restriction requirement without traverse and elected nucleic acids as the species of target analytes and bioactive agents in Paper No. 10. New claims 21-32 were added by amendment in Paper No. 10. Claims 18-32 are now pending in the present application and are being examined on their merits.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In claims 18-32, the metes and bounds claimed for the size of are not clear. Page 6 of the specification discloses that beads of 200 micrometers or less can be used but there is no definitive statement as to what sizes of microspheres are claimed.
2. Claims 18-32 recite a substrate surface comprising a plurality of assay (claim 18) or array (claim 19) locations, each assay (array) location comprising discrete sites and first and second

populations of bioactive agent. The claims also recite that "said discrete sites contain microspheres." Clarification is requested as to whether the discrete sites all contain a microsphere, a plurality of microspheres, or if some discrete sites may be empty while other discrete sites include one or more microspheres. For purposes of prosecution, it is interpreted that Applicant intends that there are more than one assay (array) locations and that each assay (array) location includes one or more discrete sites that contain zero, one, or more microspheres.

3. Claims 19 and 25-32 recite a substrate surface comprising a "plurality of array locations" indicating more than one array location per substrate surface. The claims also recite "each array location comprising discrete sites." Given that "plurality" is used in one case and not the other, it is unclear if there must be more than one discrete site in each assay location. For purposes of prosecution, it is interpreted that Applicant intends that each assay location comprise one or more discrete sites.

4. The term "substantially similar" in claim 20 is a relative term which renders the claim indefinite. The term "substantially similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The structural and/or functional relationships between bioactive agents is rendered indefinite, rendering the metes and bounds of the claim unclear.

5. The term "capable of identifying said bioactive agent" in claims 23 and 27 is confusing because it is not clear if Applicant intends the method to include the identification of "said bioactive agent" using an optical signature or not.

6. Claim 24 recites "wherein each of said subpopulations further comprise an identifier binding ligand." It is not clear if the identifier ligand is attached to each and every microsphere in each subpopulation.

7. Claim 24 recites that "the identification of the bioactive agent can be elucidated." It is not clear if Applicant intends the identification of the bioactive agent to be included in the method or not.

8. Claims 19 and 25-32 recite a first and second substrate and contacting samples contained in the first substrate with a second substrate. It is not clear how the two substrates are configured with respect to one another. For example, is each sample in each assay location contacted with a

corresponding array location on the second substrate? Is the sample contacted with a plurality of array locations simultaneously or sequentially? Without knowing the configurations of the first substrate and how they are brought together to contact sample with array, it is not possible to determine the metes and bounds of the claimed invention.

9. Claims 19 and 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the first substrate and the second substrate.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 18, 20, 22, 23, and 28-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al. (Feb. 2000, filed March, 1997) U.S. Patent No. 6,023,540.

The Walt et al. reference discloses a microsphere-based analytical chemistry system including optical encoding and an optical fiber bundle sensor (abstract). Claims 17 and 19 of the Walt et al. reference disclose a method for using an analytic chemistry sensor comprising:

- a) wells at the terminal ends of optical fibers (reads on present claim 18a(i) and 22),
- b) distributing beads within the wells (reads on present claim 18a(ii)),

- c) subpopulations carrying different chemical functionalities (reads on present claim 18a(ii)),
- d) monitoring for functionalities (reads on present claim 18b), and
- e) optically interrogatable code (reads on present claim 23).

Thus, the reference anticipates present claims 18, 22, and 23.

Claim 20 of the Walt et al. reference discloses randomly distributing subpopulations of beads within the wells, anticipating present claim 30. Claims 49 and 50 of the reference disclose nucleic acids as target analytes and chemical functionality on beads (bioactive agents), anticipating present claims 29 and 31. Claims 51 and 52 of the reference disclose enzymes and antibodies as chemical functionalities on beads (bioactive agents), anticipating present claim 32. Column 3 of Walt et al. teaches the use of dye tagged analytes and that binding of analytes to ligands on beads can change optical signatures. In such cases, the bioactive agent serves as an identifier binding ligand and the analyte as a decoder binding ligand, anticipating current claim 28.

Claims Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 18-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (Feb. 2000, filed March, 1997) U.S. Patent No. 6,023,540, Geysen (January, 1997) U.S. Patent No. 5,595,915, and Brenner (June, 1998)) U.S. Patent No. 5,763,175.

The Walt et al. reference discloses a microsphere-based analytical chemistry system including optical encoding and an optical fiber bundle sensor that anticipates claims 18, 20, 22, 23, and 29-32 as detailed in the preceding rejection under 35 U.S.C. 102 and is incorporated by reference herein in its entirety.

Walt et al. differs from the presently claimed invention in the following ways:

a) Walt et al. do not teach contacting a sample contained at a plurality of array locations of a first substrate with a second substrate comprising subpopulations of microspheres at discrete sites within array locations (present claim 19).

b) The Walt et al. reference does not teach a first substrate that is a microtiter plate.

It would have been obvious to one of ordinary skill in the art at the time that the invention was made to use more than one fiber optic array at a time in order to scale up the number of analytes that could be screened for simultaneously. The choice of vessels to contain sample solutions would also have been well within the abilities of one of ordinary skill in the art. Microtiter plates are routinely used in the combinatorial and screening arts. The Geysen reference serves to illustrate the use of multiple probes and for a sample distributed among wells in a microtiter plate. Geysen teaches a method of detecting epitopes that bind to antibodies in which the antibody sample is contained in the wells of a microtiter plate (column 3). This first substrate is contacted with a second substrate comprising peptides that are attached to the ends of rods on a solid support (second substrate). One would have had reasonable expectation of success because there would be no material changes to the method.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer

May 4, 2001

BENNETT CELSA
PRIMARY EXAMINER

